UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
BLUEFIELD DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SOUL VAPOR, LLC, a corporation, and AURELIUS JEFFREY, an individual, Defendants.	§ § § § § § § § § §	Civil Case No. 1:22-CV-00458

DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND FOR STAY

The United States is not entitled to summary judgment, nor to a stay of discovery, as explained below.

BACKGROUND

I. Soul Vapor establishment and relevant legal background

Aurelius Jeffrey opened Soul Vapor as an online store in 2015, offering a proprietary house line of open-tank e-liquids (all of which included nicotine) for sale. Defs' Exh. 1, Jeffrey decl. ¶2. In 2019, Soul Vapor established a retail location at 604 Thorn Street in Princeton, West Virginia. Soul Vapor was registered as an LLC with the State of West Virginia in early 2021. Id.

"Electronic nicotine delivery system" ("ENDS" or "vapor") products were not regulated by the Food and Drug Administration until the Secretary of Health and

Human Services issued the "Deeming Rule,"[1] 81 Fed. Reg. 28,973 (May 10, 2016), extending the application of the Food, Drug & Cosmetic Act (FDCA) to all products meeting the statutory definition of "tobacco product."[2] "Tobacco product" is defined in the statute to mean:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1).

A "tobacco product manufacturer" is "any person, including any repacker or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." 21 U.S.C. § 387(20). Accordingly, whether the registration and other requirements applicable to "manufacturers" applies to an entity turns on the "tobacco product" definition.

Defendants registered Soul Vapor as a tobacco product manufacturer with FDA in September 2018, as alleged by Plaintiff.

II. Warning Letter and Remedial Actions

[1] "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

[2] "Tobacco product" was defined in the Tobacco Control Act in 2009, but in that Act, Congress only applied federal regulation to a subset of products meeting that definition, essentially only to cigarettes and snuff, leaving out cigars and other products already on the market at that time. 21 U.S.C. § 387a(b).

Soul Vapor received the May 21, 2021 Warning Letter (ECF 11-1) as alleged by the government, notifying Soul Vapor of potential enforcement for marketing e-liquids without a marketing authorization order in place. When a representative of the CTP's Office of Compliance and Enforcement ("OCE") emailed Jeffrey on June 4, 2021, seeking to schedule a conference call to discuss the Warning Letter, Jeffrey responded within an hour and a half with his schedule for the week. Defs' Exh. 2 (Email correspondence with OCE). The conference call was conducted on June 8 (just four days after CTP's initial email). Jeffrey told CTP that he would remove the payment gateway from the website. He specifically asked Mr. Miletich if he must remove the information regarding the e-liquids from the website completely or if he could just disable the payment gateway so no purchases could be made, and Mr. Miletich said that simply removing the payment gateway would suffice. Jeffrey decl. ¶4. Jeffrey immediately emailed CTP memorializing the discussion. He wrote, in part:

> I just spoke with your office today regarding the letter and am writing to let you know what our plan of action is. I will have our team work on having the payment gateway removed from our website, soulvaporejuice.com, by the end of the week. As for the product in the vape shop, I will have the product removed from our shelves and put it in our stock room by the end of the week as well.

Defs' Exh. 2.

Defendants did exactly what Jeffrey stated in the email. Jeffrey also ceased manufacturing e-liquids with nicotine included. Instead, he began preparing mixtures of propylene glycol (PG), vegetable glycerin (VG), and flavoring, without any nicotine included in the mixture. Jeffrey decl. ¶¶6-7. Soul Vapor proceeded to sell

these products in its retail location. Soul Vapor sold nicotine separately to interested customers. Defendants believe, and still believe, that federal regulation under the FDCA does not reach VG/PG/flavor mixtures without nicotine, and therefore that Soul Vapor no longer constitutes a regulated manufacturer or processor after this change in operations. As a result of this change in operations, Soul Vapor subsequently updated its registration status with FDA, changing status from active to inactive, because Soul Vapor was no longer active in activity regulated under the FDCA. Jeffrey decl. ¶19; ECF 11-1 ¶23.

On July 19, 2021, Jeffrey received another email from CTP's Office of Compliance, stating that CTP would "like to schedule another call … to explain what further steps need to be taken." Defs' Exh. 3. Jeffrey again responded immediately, asking if the steps discussed in the prior conference were insufficient. *Id.* Jeffrey stated that, when he identified what actions he would take in the June 8 phone call, "you guys agreed that that was sufficient and just asked me to put it in writing in an email." *Id.* In the ensuing conference call, Mr. Everly stated that, although the payment gateway was removed as indicated, CTP wanted Soul Vapor to make it clearer for website visitors that the e-liquids were no longer for sale. Jeffrey decl. ¶9. Mr. Everly recommended that Soul Vapor add a statement to the website reading: "Please be advised we are no longer manufacturing our e-liquid, thus it is no longer for sale." *Id.* Defendants did so.

III. March 2022 Inspections

FDA inspected Defendants' establishment for three days between March 23 and 25, 2022. Inspection Rpt. 3.[3] FDA inspectors Matthew New and Young Kim were in Soul Vapor's establishment from approximately 9:00 a.m. to 4:30 p.m. during all three days. Jeffrey decl. ¶11. The inspectors reported that "Mr. Jeffrey participated during the inspection and answered questions and provided information." Inspection Rpt. 3. The manufacturing status, the Inspection Report states:

> The firm previously manufactured finished nicotine blended e-liquids for online and retail store customers but ceased this method of operations following their 5/21/21 warning letter from FDA. Mr. Jeffrey stated that he stopped manufacturing finished e-liquids about eight months ago and last wholesaled his products about one year ago. Following this transition, he began his current operations of separating the nicotine and flavored e-liquids and selling these two components at retail from his store.

Inspection Rpt. 8.

The inspectors observed Defendants selling Soul Vapor flavored e-liquids (*without* nicotine added), and selling liquid nicotine separately to customers who wanted nicotine, during the three days of inspections. They listened to the conversations Defendants' personnel had with customers, as explained in detail in the Inspection Report at 7. Both New and Kim were in frequent contact with superiors at the FDA during the three days of inspections, and specifically reported to FDA exactly what Defendants were doing. Jeffrey decl. ¶14. Mr. New repeatedly stated that the superiors at FDA did not know how to handle Soul Vapor's situation.

[3] The Inspection Report is attached as Exhibit B-1 to the government's motion for summary judgment (ECF 11-2).

An inspection ends with a "closeout" meeting. *See* Inspection Rpt. 10-11. During this meeting, the inspectors expressly represented that they observed no violations. Inspector New said to Jeffrey, "you're the first person we've seen do this, so there's no precedence for how to handle your situation. Any little minor changes we've requested you've done, so I don't see any issues." Jeffrey decl. ¶16. New stated that "you're not directly violating any rules." *Id.*

This conclusion is reflected also in the fact that no FDA "Form 483" was issued.

> The FDA 483, Inspectional Observations … is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts (see IOM 5.2.3.2) which were observed during the inspection. These observations are made when in the investigator's "judgment", conditions or practices observed, indicate that any food, drug, device, or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health. **The issuance of written inspectional observations is mandated by law and ORA policy**.

FDA Investigation Operations Manual at 5-20 (Defs' Exh. 4) (emphasis added). In the Inspection Report section titled, "OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE," New wrote, "An FDA 483, Inspectional Observations, **was not issued** at the closeout meeting." Inspection Rpt. 10 (emphasis added).

Instead, the inspectors advised Defendants to include a page at the front of its flavor menu book (available at the counter for customers) advising that Defendants were not selling e-liquids with the nicotine included. Jeffrey decl. ¶17.

When the inspection was over, Defendants believed that it had ended on good terms and that the matter had been resolved. *Id.* ¶18.

IV. Defendants Surprised With Litigation Demand

Defendants were therefore surprised to receive a threatening litigation demand letter dated August 31, 2022, from an attorney with the Department of Justice's Consumer Protection Branch. Defs' Exh. 5. This was the first communication from anyone with the federal government that Soul Vapor had received following the inspection that concluded there were no violations.

ARGUMENT

I. Summary Judgment Standard

"A grant of summary judgment is proper when no genuine dispute of material fact exists for trial." *Barrett v. Pae Government Services, Inc.*, 975 F.3d 416 (4th Cir. 2014). In making this determination, we view the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor." *Id.* at 168 (internal citations omitted). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

II. The Government Is Not Entitled to Summary Judgment Because The Facts Reflect a Lack of Fair Notice of the Standard of Conduct Required, or, At a Minimum, A Material Dispute of Fact Regarding Whether Notice Was Provided to Satisfy Due Process.

The first notice Defendants received that the government considered Soul Vapor's nicotine-free mixtures of PG/VG and flavor to constitute "new tobacco products" was in the August 31, 2022 DOJ letter. Not only was this the first notice of the government's new apparent reading of the law, it *directly contradicts* the

conclusion—following three days of inspections—that no violation was observed. The United States is not entitled to summary judgment because the government cannot announce a substantive standard of conduct for the first time in an enforcement action. The facts thus far reveal that Defendants did not receive fair notice of the standard of conduct required, or, at a minimum, reflect a material dispute of fact as to the sufficiency of notice that precludes summary judgment.

Due process dictates that an agency "must give the person of ordinary intelligence a reasonable opportunity to know" what is required or prohibited, so they may act accordingly. *United States v. 64,695 Pounds of Shark Fins*, 520 F.3d 976, 980 (9th Cir. 2008) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)); *see also United States v. Chrysler Corp.*, 158 F.3d 1350, 1355 (D.C. Cir. 1998); *Trinity Broad. of Fla., Inc. v. F.C.C.*, 211 F.3d 618, 628 (D.C. Cir. 2000). "It is a basic principle of administrative law that an agency cannot sanction an individual for violating the agency's rules unless the individual had 'fair notice' of those rules." *SNR Wireless LicenseCo, LLC v. Fed. Commc'ns Comm'n*, 868 F.3d 1021, 1043 (D.C. Cir. 2017). Agencies are to "provide regulated parties fair warning" of the conduct the agency "prohibits or requires" and cannot "unfair[ly] surprise" a regulated entity by penalizing it for actions taken in "good-faith reliance" on the agency's prior positions. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156-57 (2012) (quotation omitted); *see also ExxonMobil Pipeline Co. v. United States DOT*, 867 F.3d 564, 580 (5th Cir. 2017).

The fair notice requirement applies not only to formal regulations issued by an agency, but also to an agency's "other public statements," including informal, internal, or non-binding policies, positions, and representations. *See Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995); *see also Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (internal agency procedures); *PHH Corp. v. CFPB*, 839 F.3d 1, 48 (D.C. Cir. 2016), reinstated in relevant part en banc, 881 F.3d 75, 83 (D.C. Cir. 2018) (non-binding letter guidance); *ExxonMobil Pipeline Co.*, 867 F.3d at 579-580 ("extra-regulatory" source agency had previously endorsed numerous times); *Montilla v. INS*, 925 F.2d 162 (2d Cir. 1991) (internal policies and procedures). An agency acts arbitrarily and capriciously when it fails to adhere to this "[r]ule of law," *Circus Circus Casinos, Inc. v. NLRB*, 961 F.3d 469, 476 (D.C. Cir. 2020), and instead announces a new requirement at the same time it seeks to enforce it.

Any reasonable person of "ordinary intelligence" would believe that, if a three-day intensive inspection—by the very agency responsible for enforcement—concludes with the inspector expressly stating that he has not observed a violation, there was no violation. The fact that Soul Vapor's mode of operation constituted no violation of the relevant law or regulations is further demonstrated by the fact that the inspection ended without a form FDA 483. The FDA's own manual reiterates that an FDA 483 is mandatory where any violation is observed. The FDA's own website further explains this in a "Q&A" page related to Form 483. In response to the question, "When is an FDA Form 483 issued?", the agency explains: "An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s)

has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." Defs' Exh. 6. FDA explains that the "purpose" of Form 483 is to "notif[y] the company's management of objectionable conditions," with the company "encouraged to respond … in writing with their corrective action plan and then implement that … plan expeditiously." *Id.* Because no violation was found, no corrective action plan was requested or discussed.

In light of this, FDA's failure to issue a Form 483 clearly indicates the lack of a violation. In some cases, mere ambiguity in a law or regulation—where the provision could, but need not necessarily, prohibit the conduct at issue—precludes a finding of fair notice. The evidence here goes beyond that, because the inspector's express statement, and the failure to issue a Form 483, in the context of the FDA's own inspection procedures related here, provide a factual basis for Defendants to conclude that their conduct was not in violation. The government now, retroactively, cites the *2016 Deeming Rule* to support its recent apparent decision to treat PG/VG/flavor blends lacking nicotine as "flavorings used with ENDS products" regulable as "components or parts" of a "tobacco product." *United States' Mtn. for Summ. Judg.* at 12. But the 2016 Deeming Rule was obviously extant in March 2022, when FDA's own inspectors concluded there was no violation. Whether FDA's apparent current interpretation of the relevant definitions to capture the activity here is permissible or not—an issue certainly subject to debate—the record does not reflect that Defendants had fair notice of such interpretation as a matter of law.

III. The Government Has Not Established That Defendants' Updated Registration Status with FDA Is Misleading.

There is no question that Defendants changed the registration status of Soul Vapor with the FDA, but the government cannot show that the change is misleading.

Ms. Ibarra-Pratt, Deputy Director for Regulatory Affairs in the Office of Compliance and Enforcement, references the registration requirement at 21 U.S.C. § 387e, and claims, conclusory, that Soul Vapor's changed status was misleading. ECF 11-1 ¶¶13, 22-24. However, if Soul Vapor is not currently engaged in the "manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" as defined in the law, then this registration requirement does not even apply to Soul Vapor.

As with the preceding section, definitions are important, notwithstanding the government's penchant for overlooking them. The relevant statute states that, "[o]n or before December 31 of each year, every person who owns or operates any establishment in any State **engaged in the manufacture, preparation, compounding, or processing** of a **tobacco product or tobacco products** shall register with the Secretary[.]" 21 U.S.C. § 387e(b) (emphasis added). The phrase "manufacture, preparation, compounding, or processing" is itself defined to mean "repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." *Id.* § 387e(a)(1).

As New's Inspection Report reflects, Defendants were completely candid regarding their response to the May 2021 Warning Letter, and the inspectors

observed their new mode of operating for three full days. Defendants no longer produced finished e-liquids with nicotine included; they produced mixtures of PG/VG and flavors, and had nicotine available separately for interested customers. This change in operation was made in June 2021, and Soul Vapor's registration status was updated in September. Once again, although this status change was made six months before the inspection, the Inspection Report identifies no violations. In fact, the Report recounts Soul Vapor's new mode of operations, explaining under the section for "VOLUNTARY CORRECTIONS," that:

> Mr. Jeffrey stated that he believed this issue to be resolved since he no longer "manufactures" these products because he stopped combining/mixing/blending nicotine into flavored e-juices. He ascribes that since he does not meet the technical definition of a "tobacco manufacturer" that he has corrected this issue. He has separated the production process and sells raw nicotine and the flavors in two separate containers for customers to blend after they purchase the products and believes that he has resolved the marketing authorization issue.

Inspection Rpt. 11-12.

This reflects that the FDA's inspectors were well aware in March 2022 of exactly what Defendants were doing, and, critically, the Inspection Report describes it without any notation that Jeffrey's explanation was rejected by the inspector or an incorrect understanding of the law.

IV. Summary Judgment is Premature Without the Opportunity for Discovery.

No discovery has been conducted in this case yet beyond exchange of initial disclosures. The evidence that is in the record thus far, including the Inspection Report, *preclude* any summary judgment for Plaintiff because, at a minimum, even the government's own exhibits reflect a material dispute regarding provision of fair

notice, required by due process, before enforcement was undertaken. Nonetheless, the lack of any discovery thus far provides another reason that summary judgment should be denied. *See Harrods, Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244-45 (4th Cir. 2002). The Plaintiff's stay motion should be denied, as Defendants are entitled to the opportunity to conduct discovery in the normal course.

Defendant anticipates that, in light of the evidence in the Inspection Report and Jeffrey's declaration, the United States will attempt to explain away or minimize the meaning of the statements in the Inspection Report, or the failure to issue a Form 483 at the end of the inspection. Defendant is entitled to the opportunity to develop additional relevant evidence, which will include, but is not limited to:

- The ATT Inspection Memorandum, Directed Inspection Request, mentioned in the Inspection Report at 12 (which may provide evidence of FDA's understanding of the scope of the relevant definitions);
- Written communications between the inspectors and FDA officials;
- Any internal FDA documents that would reflect FDA's interpretation of the relevant provisions both before and after the inspection of Defendant, including evidence reflecting when the FDA made the apparent decision to find a violation despite the contrary conclusion by its inspectors, and any claimed evidence of notice that FDA intends to rely upon.
- Internal documents reflecting FDA policy and practice regarding the issuance of Form 483 and the circumstances in which one is and is not issued, and the implications of same.

Counsel has attached to this response a verification of these statements. *See* Fed. R. Civ. P. 56(d).

V. Objection to Proposed Terms of Injunction

The government is not entitled to summary judgment, for the reasons explained above. But even if it were, the FDA's proposed injunction includes provisions that exceed any statutory authorization for injunctions in these circumstances. In fact, the vast majority of the proposed terms are improper, even if an injunction were otherwise appropriate under the FDCA. While the government claims that materially similar injunctions have been issued as part of consent decrees in other district courts, the government makes no representation that a single defendant in any such case actually opposed it or attempted to litigate, much less that any such case involved a defendant who was operating as Soul Vapor was, selling nicotine-free PG/VG/flavor mixtures and separate nicotine. This issue of the proper scope and terms of an injunction deserves full consideration at the appropriate time—if it were to become necessary at all—and Defendants hereby request the opportunity to develop their arguments at that time. Here, Defendants point out at least some of their objections in preliminary form.

The government itself relies on the particular statutory authority for injunctions under the FDCA (ECF 12 at 15, citing 21 U.S.C. § 332(a)) in order to argue that it is not required to establish the traditional elements of injunctive relief, but then simultaneously proposes an injunction that goes far beyond the injunctive relief contemplated by the same authority. The government cannot have it both ways. The statute authorizes courts to "restrain violations of Section 331" of the FDCA, not to impose gratuitous provisions requiring payment of inspection fees for any future inspections when a regulated entity wishes to sell authorized products; or any prior

restraint on sales of *authorized* products unless and until the FDA conducts an inspection at its leisure, charges the entity for such inspection, and then issues a written report with no timetable for completion of such report (¶3(C), (D), and (E)); or provide any new and expanded inspection authority beyond that already authorized in the FDCA (¶8). The proposed injunction goes far beyond that contemplated even in the DOJ's surprise litigation demand, which stated an injunction would be sought to prohibit Soul Vapor from essentially selling or manufacturing any products that do not have a marketing authorization order in place. That kind of injunction would be consistent with the authority in Section 332(a), but not the injunction sought by the government now.

CONCLUSION

Plaintiff's motion for summary judgment should be denied. Defendants further request any additional relief to which they may be entitled.

Respectfully submitted,

/s/ Caleb B. David
Caleb B. David
West Virginia Bar No. 12732
Shuman McCuskey Slicer PLLC
1411 Virginia Street, East, Suite 200
Charleston, WV 25301
Phone: (304) 345-1400
Fax: (304) 343-1826
cdavid@shumanlaw.com
Counsel for Defendants

Jerad Wayne Najvar
Texas Bar No. 24068079
jerad@navjarlaw.com

NAJVAR LAW FIRM PLLC
2180 North Loop West, Suite 255
Houston, TX 77018
Phone: (281) 404-4696
Facsimile: (281) 582-4138
Counsel for Defendants

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing **DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND FOR STAY** was served via CM/ECF on March 16, 2023, as follows:

JOSHUA A. BROWNING
DC Bar No. 1510857
Trial Attorneys
P.O. Box 386
Washington, D.C. 20044
Phone: (202) 451-7731
Ellen.Bowden.McIntyre@usdoj.gov
Joshua.A.Browning@usdoj.gov
Counsel for Plaintiff

STEPHEN C. TOSINI
DC Bar No. 470415
Senior Trial Counsel
United States Department of Justice
Civil Division
P.O. Box 480
Ben Franklin Station
Washington, DC 20044
Stephen.Tosini@usdoj.gov
Counsel for Plaintiff

JENNIFER M. MANKINS
W. Va. Bar No. 9959
Assistant United States Attorney
United States Attorney's Office
300 Virginia Street East, Room 4000
Charleston, WV 25301
Phone: (304) 345-2200
Fax: 304-347-5443
Email: Jennifer.Mankins@usdoj.gov
Counsel for Plaintiff

/s/ Caleb B. David
Caleb B. David (WVSB #12732)